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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,377	02/07/2002	Timothy B. Karpishin	269/003	1762
25226	7590	04/18/2005		
MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			EXAMINER COLEMAN, BRENDA LIBBY	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 04/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

VV

<b>Office Action Summary</b>	<b>Application No.</b> 10/071,377	<b>Applicant(s)</b> KARPISHIN ET AL.	
	<b>Examiner</b> Brenda L. Coleman	<b>Art Unit</b> 1624	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 January 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 8-10, 12-25, 33-35, 39-41 and 46-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 11, 26-32, 36-38 and 42-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/28/05</u> . | 6) <input type="checkbox"/> Other: _____  |

*[Handwritten signature]*

### **DETAILED ACTION**

Claims 1-49 are pending in the application.

This action is in response to applicant's amendment dated January 8, 2005.

Claims 4, 5, 26, 42 and 44 were amended.

### ***Response to Arguments***

Applicant's amendments and arguments filed January 8, 2005 have been fully considered with the following effect:

1. The applicants' stated with respect to the election/restriction that any generic claims be found allowable, the Manual of Patent Examining Procedure, Eighth Edition § 809.02(c)(B), require that nonelected species that are fully embraced by the allowed generic claim no longer be withdrawn. The applicants are reminded that the restriction was set forth such that an election was required between VI groups and that is was not an election of species.
2. Claims 8-10, 12-25, 33-35, 39-41 and 46-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 22, 2004.
3. The applicants are also reminded that a search of the claims conducted in June 2004 to the elected invention was on macrocyclic modules which comprise three 1,3-phenylene rings and three 1,2-cyclohexane rings linked together by -C~N- where the nitrogen atom is bonded to the cyclohexane rings.

4. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 1-7, 11, 26-32, 36-38 and 42-45, the applicants' amendments and remarks have been fully considered but they are not found persuasive. The applicants' stated that the synthesis of core synthons are provided in Schemes 1-6 on pages 27-33, including 1,3-diaminocyclohex-5-ene, 1,2-diaminonorborane, and 1,3-diaminonorborane (the latter two are bicyclic[2.2.1]heptenes) and that the specification teaches the requirements for the synthons, e.g. the linking groups and other desired moieties, and demonstrates how to make certain synthons. As stated in prior office actions the nature of the invention in the instant case, has claims which embrace macrocyclic compounds which contain three to twenty four cyclic synthons which are coupled together with a linker of which the number and nature of the cyclic synthons and/or linking groups are extensive and complex. The instant specification only teaches three examples where each of the examples are 2 or 3 phenylenes and 2 or 3 cyclohexanes, respectively of which each of the phenylenes and each of the cyclohexanes are identical. The applicants also stated that the reactions necessary to provide suitable synthons are sufficiently predictable from the guidance given by the reaction schemes and examples in the specification. However, the reaction between pyridines for example where the carbon atom in the 2-position versus the 4-position varies with respect to nitrogen pull as well as other reaction conditions.

In view of the lack of direction provided in the specification regarding starting materials, the lack of working examples, and the general unpredictability of chemical reactions, it would take an undue amount of experimentation for one skilled in the art to

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make the claimed compounds and therefore practice the invention. To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. The applicants' are not entitled to preempt the efforts of others. The test for determining compliance with 35 U.S.C. § 112 is whether the applicants have clearly defined "their" invention not what may be discovered by future research.

Claims 1-7, 11, 26-32, 36-38 and 42-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

5. The applicants' amendments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 6 in the last office action, which are hereby **withdrawn**.

The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection labeled paragraph 7 in the last office action, which are hereby **withdrawn**.

6. With regards to the provisional obviousness-type double patenting rejection as being unpatentable over copending Application No. 10/226,400 of the last office action, the applicants requested that this rejection be held in abeyance at this time.

Claims 1-7, 11, 26-32, 36-38 and 42-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims 1-40 of copending Application No. 10/226,400, for reasons of record.

In view of the amendment dated January 8, 2005, the following new grounds of rejection apply:

***Specification***

The disclosure is objected to because of the following informalities:

- a) The amendment to paragraph [0016] has the definition of two variables, which are not present in the formula, i.e. R17 and R18. It is believed that the applicants intended R<sup>17</sup> and R<sup>18</sup>.
- b) The amendment to paragraph [0058] has the definition of two variables, which are not present in the formula, i.e. R19 and R20. It is believed that the applicants intended R<sup>19</sup> and R<sup>20</sup>.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

- 7. Claims 4 and 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claim 4 is vague and indefinite in that it is not known what is meant by the moiety  $-\text{O}(\text{CH}_2)_y\text{-oxiran-2-yl}$ , where the repeater for the  $(\text{CH}_2)$  group is not a subscript.
- b) Claim 30 is vague and indefinite in that it is not known what is meant by the moiety  $-\text{NH}_2$ , where the repeater for the H atom is not a subscript.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda L. Coleman  
Primary Examiner Art Unit 1624  
April 12, 2005